

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In r Application of)
Bradford C. Webb)
Serial No.: 08/055822)
Filed: April 4, 1993)
For: Synthetic Viscoelastic)
Material for Ophthalmic)
Applications)

Declaration of Bradford C. Webb
Submitted Under 37 CFR 1.132

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Sir:

I, Bradford C. Webb declare that:

1. I am the inventor of the Synthetic Viscoelastic Material for Ophthalmic Applications claimed in the United States Patent Application 08/055,822 filed April 4, 1994. I am also the president of Vision Biology, Inc., assignee of record of the application.

2. I have read the claims of the subject patent application. I am thoroughly familiar with the product claimed therein, the product being manufactured by Vision Biology, Inc. under the name Cellugel™ materials, and the medical requirements of such a product.

3. I have personally prepared the Cellugel™ materials product in accordance with the teachings of said application and the claims now pending and do represent and declare that the Cellugel™ materials product supplied to Drs. Hunkler and Livernois are fully within the claims as originally filed and as now pending.

4. Cellugel™ materials is a high viscosity, high molecular weight cellulosic based viscoelastic material for use principally during ophthalmic surgery, particularly cataract surgery, to protect the delicate eye tissue and to maintain the volume of the eye.

5. Cellugel™ materials are not subject to many of the drawbacks of other cellulosic viscoelastic materials used for the same purposes.

6. Every other cellulosic viscoelastic material has a viscosity of about 3,000 to 4,000 centipoise at 25°C. This is significantly less than the natural material found in the eye (the vitreous humor) or other viscoelastic materials used for this purpose. As a result, when one of these prior art cellulosic materials is used to augment the eye's natural material during surgery, the volume in the eyeball is not properly maintained, thus interfering with surgical procedure and exposing the eye tissue to damage from surgical instruments. This represents a major drawback in the use of these materials. Cellugel™ materials, however, have a static viscosity of about 40,000 centipoise at 25°C. The higher viscosity of Cellugel™

materials, allow them to be used during cataract surgery without running the risk of internal eye volume decreasing and reduces the risk of damaging delicate tissue with instruments or artificial lenses.

7. Another significant problem associated with prior art cellulosic based viscoelastic materials is the presence of particulates in these materials. Particulates are a problem in cellulosic ophthalmic materials in two ways. First, although efforts are generally made to remove the ophthalmic material from the eye after cataract surgery, it is inevitable that some will be left inside the eye. The particulates in this material may then interfere with the free flow of the eye's natural aqueous fluid through the trabecular meshwork. When a portion of this meshwork is plugged by particulates, high intraocular pressure may result. Unless corrective action is taken, this pressure may cause blindness.

8. The second problem caused by particulates in the cellulosic viscoelastic material is that they may reduce the transparent quality of the material. An ophthalmic surgeon depends on a highly transparent material to allow visualization into the area where the surgery is taking place. Anything which tends to obscure this view can significantly increase the risk of surgery.

9. Cellugel™ materials have virtually no particulate contamination, due to the claimed process of repeated filtering for

particulates and repeated resuspension of the solution. As a result, post operative build up of intraocular pressure is less likely. In addition, the surgeon is benefitted by a clear view of the surgical area.

10. Prior art cellulosic based viscoelastic materials are not always free of dissolved gas and bubbles when provided by the manufacturer. Suspended bubbles or bubbles released from the viscoelastic material following injection into the eye and application of ultrasonic phacoemulsifiers to the cataract lens can interfere with the surgeon's view of the operating area in a similar manner to the way particulates interfere with this view. Any interference with the surgeon's view, increases the risk of error during an operation.

11. Cellugel™ materials are more highly lubricous than the prior art materials. They achieve this high lubricity while having a high viscosity. The lubricous material coating the tissue prevents damage should the instruments or artificial lenses come into contact with the extremely delicate tissues in the eye.

12. The unique and heretofore unknown properties of Cellugel™ materials are neither obvious nor even suggested by a study of this substance's constituent components. In fact, such a review teaches away from the invention of Cellugel™ materials as a material for use in ophthalmic surgery as it suggests that the resultant

material would have qualities that would preclude it from this sort of use.

13. A review of the attached viscosity vs. concentration curves, provided to me by Dow Chemical Co. indicates that a 3.0% solution of a 1:2 by weight mixture of Methocel K100M and Methocel E10M CR (the two ingredients, other than physiological saline of Cellugel™ materials) when mixed as directed in the patent application would result in a material with a viscosity of 266,000 centipoise, rather than the 40,000 centipoise actually found in Cellugel™ materials. A viscosity of 266,000 centipoise is too high for use in ophthalmic surgery.

14. Additionally while the purification process starts with a 3% solution of a 1:2 ratio of materials the end product is a 2.3% mixture of materials which clearly does not have an average molecular weight predicted by blending the two starting materials.

15. Nothing in the technical information concerning the properties of Methocel K100M and Methocel E10M, suggest that their mixture would result in a material with a viscoelastic quality or that this material could be adequately filtered to remove particulate matter therein.

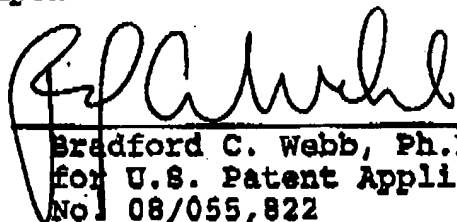
16. The unexpected properties of Cellugel™ materials are due to the inventive filtering process which removes the particulates

and undesirable molecular weight components. Not only are these components potentially detrimental to the system, they also contribute to an unacceptable static viscosity. They do not, however, contribute to the viscoelasticity.

DECLARATION

17. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that all statements were made with the knowledge that willful false statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the application or any patent issuing thereupon.

Dated: March 10, 1994


Bradford C. Webb, Ph.D.
for U.S. Patent Application
No. 08/055,822